SEP 27 2005 K052235

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:..... 3M ESPE
Street:..... 3M Center Bldg 260-2B-12
City, State, Zip-code: ..... St. Paul, MN 55144
Country: ..... U.S.A
Establishment Registration Number:. 2110898
Contact:..... Karen O'Malley
Regulatory Affairs Specialist
Phone:..... 651 736-7326
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Date of Submission:..... August 9, 2005

Name of Device

Proprietary Name:..... LCR
Classification Name: ..... Dental Cement
Common Name:..... Glass Ionomer Restorative

Predicate Devices:

Vitremer Core Buildup/Restorative System..... K925032
Photac-Fil Aplicap K925027
Fujii II LC.....K993973

LCR is classified as a Dental Cement (21 C.F.R. § 872.3275) because it is a resin modified glass ionomer base cement used as a temporary tooth filling.

3M ESPE is submitting this Special 510(k) for modifications to Vitremer Core Buildup/Restorative System (K 925032). The modifications of Vitremer Core Buildup/Restorative System are minor changes of the chemical composition, while the basic chemical design remains the same. The change results in primarily change to the physical form of the delivered product and the means to dispense the product for placement in the dental procedure. A summary of the design change features is:

- Paste/ paste bulk and unit dose delivery system for ease of mixing and delivery as compared to existing powder/ liquid systems.
- Consistent cement properties because of exact mixing ratio
- Less preparation and clean-up steps
- Improved wear and polishability of the restoration
- Improved esthetics of the restoration

LCR is designed to retain the excellent physical, mechanical and clinical properties of existing Vitremer Core Buildup/Restorative System. Like Vitremer Core Buildup/Restorative System, LCR has the same basic chemical composition and material characteristics for patient application. LCR is a light curing, radiopaque, fluoride-releasing, resin-modified glass ionomer restorative system. The restorative system consists of a base and catalyst paste and a primer. LCR is available in 8 shades. The restorative paste will be available in both the multi-dose 3M ESPE Clicker dispensing system or a unit dose option.

The modified light-curing glass ionomer restorative system, LCR, has the following similarities to the currently marketed Vitremer Core Buildup/Restorative System:

- Both restoratives have the same intended use.
- Both are resin modified glass ionomer cements incorporating the same major chemical components.
- Both restoratives have the same shelf life and storage conditions.

To provide evidence for safety, the chemical composition of LCR was compared to Vitremer Core Buildup/Restorative System. Additionally, independent research institutes carried out biocompatibility testing. The results show that LCR is a safe device when used as directed. To demonstrate the effectiveness of LCR, the performance characteristics of LCR were compared to 3M ESPE Vitremer Core Buildup/Restorative System, 3M ESPE Photac-Fil Aplicap and GC FujiII LC.

In summary, the modified dental restorative system, LCR, described in this Special 510(k) pre-market notification submission is substantially equivalent to the predicate devices. This is our position with regard to intended use, major chemical components, shelf life, storage conditions, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Ms. Karen O'Malley
Regulatory Affairs Specialist
3M Company
3M Center, Building 260-2B-17
St. Paul, Minnesota 55144-1000

Re: K052235
Trade/Device Name: LCR, Light-Curing Glass Ionomer Restorative System
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: September 9, 2005
Received: September 12, 2005

Dear Ms. O'Malley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052235

Device Name: LCR, Light-curing glass ionomer restorative system

Indications for Use:

Primary teeth restorations

Small Class I restorations

Class III and Class V restorations

Transitional restorations

Filling defects and undercut areas in crown preparations

Core buildup where at least half the coronal tooth structure is remaining to provide structural support for the crown

Laminate sandwich technique

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K052235